DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Radscan Medical Equipment, Incorporated
C/O Ms.Dawn Tibodeau
Responsible Third Party Official
TÜV SÜD America, Incorporated
1775 Old Highway 8 NW
New Brighton, Minnesota 55112-1891

JAN - 4 2011

Re: K101350
Trade/Device Name: RadScan Equipment Slicker
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: II
Product Code: KKX
Dated: December 17, 2010
Received: December 20, 2010

Dear Ms. Tibodeau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

JAN - 4 2011

510(k) Number (if known): K101350

Device Name: RadScan Equipment Slicker®

Indications For Use: This single use sterile equipment cover is intended for use by professionals in a sterile clinical setting to cover and prevent contamination of non-patient contact equipment during various procedures. The following current models are the subject of this filing.

RadScan Equipment Slicker Models				
Part No. Suffix -XXV	A - Length In. (cm.)	B - Width In. (cm.)	C - Min. Band Opening In. (cm.)	Label Suffix -0XX
DP-SSIP-01V	21¾ (55.2)	19¾ (50.2)	9½ (24.1)	RME-LBL-001
DP-SSIP-02V	12 (30.5)	8 (20.3)	3½ (8.9)	RME-LBL-002
DP-SSIP-03V	28 (71.1)	12 (30.5)	5½ 14.0)	RME-LBL-003
DP-SSIP-04V	31 (78.7)	21¾ (55.2)	10½ (26.7)	RME-LBL-004

Future models will continue the part / label number sequences, and will be identical in materials, constructions, and indications for use, except for dimensions A, B, & C.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie-Williams

(Division Sign-Off)
Division of Anesthesiology. General Hospital
Infection Control, Dental Devices

510(k) Number: K101350